UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

THE PROCTER & GAMBLE COMPANY,	)	
	)	
Plaintiff,	)	**Civ. No. 07-8379 (RJS)**
	)	
v.	)	**ECF Case**
	)	
ULTREO, INC.,	)	
	)	
Defendant.	)	

DEFENDANT ULTREO, INC.'S PROPOSED FINDINGS OF FACT AND CONCLUSIONS OF LAW

WINSTON & STRAWN LLP

Anthony DiSarro
Lina M. Viviano
200 Park Avenue
New York, NY 10166
(212) 294-4600
adisarro@winston.com
lviviano@winston.com

Kimball R. Anderson
Stephen P. Durchslag
35 West Wacker Drive
Chicago, IL 60601

KIRKPATRICK & LOCKHART PRESTON GATES ELLIS LLP

Marc C. Levy
925 Fourth Avenue, Suite 2900
Seattle, WA 98104

Attorneys for Defendant Ultreo, Inc.

TABLE OF CONTENTS

PROPOSED FINDINGS OF FACT

A. Background

1. Ultreo is a small company located in Redmond, Washington, that manufactures and sells a single product – the Ultreo power toothbrush. (Gallagher Dir. ¶ 33). Ultreo was formed in 2003 by former scientists and executives of Optiva, the company that developed the Sonicare power toothbrush that is currently sold by Philips Oral Healthcare Inc. ("Philips"). (*Id.* ¶¶ 2, 5). After several years of extensive research and testing, Ultreo developed a power toothbrush that combines ultrasound technology with sonic bristle action. (*Id.* ¶¶ 9-11).

2. The sonic action bristles on the Ultreo remove plaque and create bubbles. (Gallagher Dir. ¶ 46). A transducer located within the brushhead generates ultrasound waves which are then directed via a waveguide into the fluid located around the bristle tips. (*Id.* ¶ 9; Crum Dir. ¶ 14). These ultrasound waves cause the bubbles in the fluid environment to oscillate (move rapidly) and pulsate (increase and decrease in size). (Gallagher Dir. ¶ 9; Crum Dir. ¶ 10). This process, known as cavitation, has been shown in laboratory tests to remove plaque bacteria from a simulated tooth surface. (Crum Dir. ¶¶ 12-15). This cavitation process is similar to that by which ultrasound waves are used to clean jewelry, surgical equipment and other objects. (Crum Dir. ¶¶ 9-11).

3. Prior to launching the Ultreo in February 2007, Ultreo sponsored a series of clinical studies conducted by an independent clinical research firm that demonstrated that the Ultreo was effective in removing plaque, reducing gingivitis and removing stains on teeth. (McInnes Dir. ¶¶ 9-12). These studies, while demonstrating that the product is efficacious, do not identify what portion of the results are attributable to the sonic brushing action as opposed to the ultrasound waves. (Berg Dir. ¶ 10). Consequently, Ultreo does not claim in any of its

advertising that clinical tests prove that the ultrasound waves or the bubbles activated by the ultrasound, by themselves, can remove plaque bacteria. (Gallagher Dir. ¶¶ 47-49).

4. Ultreo has, however, sponsored a laboratory study conducted at the University of Washington ("UW Study"), in which the Ultreo toothbrush, in the absence of physical bristle contact, was shown to remove a representative form of plaque bacteria from simulated tooth surfaces. (McInnes Dir. ¶¶ 14-17). The methodology for this study, which is known in the scientific community as an *in vitro* plaque biofilm removal study, has repeatedly been used by Philips, the market leader for premium power toothbrushes, to support claims regarding the Sonicare toothbrush. (Berg Dir. ¶¶ 13-21).

5. Ultreo relies upon the UW Study to make claims to dental professionals regarding the ability of the ultrasound component of its product to enhance its plaque-removal capabilities. (McInnes Dir. ¶¶ 48-49). Such claims are generally referred to in the industry as "beyond-the-bristles" claims. (Berg Dir. ¶ 15). For years, Philips has made, and today continues to make, beyond-the-bristles claims for its Sonicare brush, contending that the sonic bristle action generates fluid streaming forces that remove plaque where the bristles cannot reach. (McInnes Dir. ¶¶ 18-28; Berg Dir. ¶¶ 15-16; DX 14-21, 186).

6. Ultreo has marketed its toothbrush to dental professionals through advertising in professional journals and by direct marketing. (Gallagher Dir. ¶ 15). Wherever Ultreo makes an express beyond-the-bristles claim to those professionals, it plainly discloses that the claim is based upon a laboratory study. (Gallagher Dir. ¶¶ 47-48; DX 13).

7. Ultreo also sells its product to consumers via internet retailers, such as amazon.com, specialty stores, such as The Sharper Image, catalog retailers, such as Frontgate, and certain major retailers, such as Macy's. (Gallagher Dir. ¶¶ 18-19). Ultreo does not make express beyond-the-bristles claims to consumers. (*Id.* ¶ 41).

8. Having just entered the market in 2007, Ultreo has no market share.

(Gallagher Dir. ¶ 30).

9. P&G is the manufacturer of the Oral-B brand of power toothbrushes. It has $76 billion in total sales and controls 38% of the market for premium power toothbrushes. Philips has about $39 billion in sales and controls the remaining 62%. (Rao Dir. ¶¶ 6, 13; Randall Decl. ¶ 6).

10. On September 27, 2007, P&G filed this lawsuit against Ultreo and moved for a preliminary injunction seeking to temporarily restrain certain express and alleged implied claims made by Ultreo. P&G's primary contention is that Ultreo is making an implied beyond-the-bristles claim to consumers and that this implied claim, as well as the express beyond-the-bristles claim made to dental professionals, are false because they are not supported by an *in vivo* human clinical study.[1]

B. Express Claims By Ultreo To Consumers

11. Although P&G's moving papers challenged a number of express claims that Ultreo makes to consumers, P&G conceded at the hearing that these claims were truthful. P&G's Vice President of Oral Care, Wayne Randall, admitted that each of the following express claims to consumers is true:

- Sonic action bristles with power tips clean away plaque upon contact and create microbubbles. (Tr. at 89).
- Ultreo is the first power toothbrush to combine patented waveguide technology with precisely tuned sonic bristle action. (Tr. at 90).

[1] Shortly before closing arguments on January 11, P&G submitted a chart of claims it was still challenging on the motion. Annexed hereto as Exhibit A is an annotated version of that chart, which summarizes Ultreo's position regarding these claims and which references the paragraphs of this submission that support Ultreo's position.

- Ultreo's bristles create microbubbles that are powerfully activated by nearly 4 million cycles of ultrasound energy per brushing channeled by a patented ultrasound waveguide. (Tr. at 90).
- Ultreo's combination of patented ultrasound technology and sonic bristle action can remove hard-to-reach plaque for an incredibly deep feeling of clean (Tr. at 90).[2]
- Ultreo has been clinically proven to remove up to 95 percent of plaque from hard-to-reach areas in the first minute of brushing. (Tr. at 91).

12. Mr. Randall further acknowledged that Ultreo makes no comparisons in its advertising with the Oral-B or any other power toothbrushes. (Tr. at 92). Consequently, P&G cannot claim that Ultreo is making any express or implied superiority claim *vis-à-vis* competing products.

13. P&G also concedes that certain express claims made by Ultreo are puffery. They include claims about "taking power brushing where it's never gone before," which Mr. Randall admitted is puffery (Tr. at 89-90), and references to the term "magic," which P&G does not deny is puffery.[3]

C. Statements By Third Parties

14. The only remaining express claims to consumers that P&G challenges are statements made by third parties. For example, P&G takes issue with certain statements concerning the Ultreo contained in articles reviewing the product that were published in magazines or on websites such as *MetroSource*, *NotCot.com*, *Complex Magazine* and *Popular Science*. (Tr. at 808-10). These statements, however, are made by the authors of those publications, not Ultreo (Tr. at 277), and there is no evidence that Ultreo caused any of these

---

[2] Mr. Randall testified that this claim, "on its face," is "probably true," although it can be "misleading" depending on the context (Tr. at 90-91).

[3] Ultreo has introduced evidence showing that P&G repeatedly uses the term "magic" in its own advertising. (Gallagher Dir. ¶ 57; DX 25-26).

allegedly false statements to be made. Nor is there any evidence that Ultreo uses any of these articles or statements in connection with any of its own advertising claims. Ultreo merely offers consumers access to these and many other articles from its website. (Tr. at 277-78). Notably, P&G's Oral-B website also links users to magazine articles that favorably mention its power toothbrushes. (*See, e.g.*, Oral-B website page (DX 202) annexed hereto as Exhibit D).

15. P&G also challenges the following statement contained in an advertisement that was run by a third-party retailer, Frontgate, in a *SkyMall* catalog: "The sonic brush creates bubbles that pulsate at an exact ultrasonic frequency of optimal plaque removal." (PX 59; Gallagher Supp. Decl. Exhibit C). This is Frontgate's language, not Ultreo's. (Gallagher Supp. Decl. ¶ 16). Ultreo's suggested copy for that ad did not contain the sentence at issue, but Frontgate chose to use its own language. (DX 197-98). Ultreo has not made use of Frontgate's language in its own advertising, nor is the *SkyMall* ad accessible from Ultreo's website. (Gallagher Supp. Decl. ¶ 16). In any event, Ultreo has requested that Frontgate remove the sentence from its future ads, and Frontgate has agreed to do so. (Gallagher Supp. Decl. ¶ 15).

D. Alleged Implied Beyond-The-Bristles Claim To Consumers

16. P&G contends that Ultreo is making an implied beyond-the-bristles claim to consumers. P&G's contention is based primarily upon a consumer survey conducted by Dr. Thomas Dupont (the "Dupont Survey") utilizing a few selected (and redacted) pages from Ultreo's website.

1. The Dupont Survey

17. The Dupont Survey did not employ a control group. That is, it did not measure an Ultreo advertisement containing the language and visuals that P&G alleges give rise to this implied beyond-the-bristles claim, against an advertisement not containing those words or pictures. (Wind Dir. ¶ 6). The use of a control group is essential to draw reliable conclusions

about the effects of a particular form of advertisement. (Wind Dir. ¶ 6). Dr. Dupont acknowledged that employing a control was something that could have been done in this case, but was not done. (Tr. at 221-22).

18. Dr. Dupont contended that a control group was not needed because he "did not believe that there were any pre-existing beliefs" about ultrasound or "preconceived notions about bubbles" that could influence respondents. (Tr. at 194-96). Yet, Dr. Dupont conducted no research (other than asking P&G's counsel) to determine whether the cleaning potential of bubbles was ever used in oral care advertising. (Tr. at 200).

19. Ultreo introduced numerous examples of advertisements relating to the cleaning potential of bubbles with respect to both toothpastes and toothbrushes. (Tr. at 412-18; DXs 14, 181-85). Furthermore, several of the actual verbatims to Dr. Dupont's survey reveal that respondents did in fact have pre-existing perceptions concerning ultrasound and its cleaning ability, some of which were based on their familiarity with the Sonicare brush. (DX 105 at PG 000079-81).

20. Moreover, because the web pages that Dr. Dupont tested contained statements that P&G claims are objectionable, as well as statements that P&G concedes are truthful, the Dupont Survey cannot determine whether, and to what extent, the objectionable language is responsible for producing the consumer perceptions reported in the study. (Tr. at 221-23). For instance, P&G contends that the Dupont Survey shows that consumers took away a beyond-the-bristles message from the stimulus because many respondents said they understood a "feeling of clean" to mean "clean teeth." However, Dr. Dupont acknowledged that the admittedly truthful statements in the tested web pages regarding Ultreo being clinically proven to reduce gingivitis, and the fact that eight out of ten consumers said that they felt that Ultreo cleaned better than their regular powered toothbrush, might very well have informed respondents' understanding of a

"feeling of clean." (Tr. at 223-24). Thus, there is no way to tell whether consumers' perceptions of the term "feeling of clean" is attributable to the language to which P&G objects.

21. Dr. Dupont never asked the respondents the general open-ended question of what they perceived the message, or primary messages, of the ad to be. (Tr. at 203). This type of question is routinely used in consumer surveys. (Wind Dir. ¶ 8). Instead, he employed leading questions designed to cause respondents to focus on ultrasound. (Wind Dir. ¶ 9). These leading questions included:

- Based on what you saw, do you think the Ultreo toothbrush is different from other toothbrushes, or not?
- In what you read, do you recall them mentioning that Ultreo used ultrasound technology?
- What does the ultrasound do?
- What is the benefit of the ultrasound?
- What is the benefit of having a deep feeling of clean?

(Wind Dir. ¶ 9; DX 105 at PG 000035). It is only through these leading questions that the Dupont Survey was able to achieve the results upon which P&G relies.

22. Significantly, Dr. Dupont did not use the actual web pages from the Ultreo website as the test stimulus for his survey. (Wind Dir. ¶ 8). Instead, he cherry-picked a few pages from the site and then redacted material from those pages. This materially altered the stimulus from the version that is seen by actual consumers. He also tested web pages that are different from the current versions. (*Id.*). Thus, the Dupont Survey is not a reliable indicator of how actual consumers would read the actual material that is presently being used on Ultreo's website. (*Id.*).

23. Dr. Dupont also inappropriately conflated survey responses. (Wind Dir. ¶ 12). He aggregated all responses that mentioned either ultrasound, or bubbles or sonic vibrations.

(Tr. at 182). He did this because he did not understand the distinction between sonic vibrations, which relates to the physical bristle movement of the Ultreo, and ultrasound, which is emitted from the transducer and channeled by the waveguide. (Tr. at 182). This critical failure renders the Dupont Survey incapable of determining the number of respondents that took away any implied message that ultrasound removes plaque. (Wind Dir. ¶ 12).

2. Alleged Intent To Imply Beyond-The-Bristles Cleaning To Consumers

24. P&G further contends that by making "feeling of clean" claims,[4] Ultreo intends to communicate an implicit beyond-the-bristles cleaning message to consumers. However, P&G adduced no evidence of such intent. To the contrary, the evidence shows that a "feeling of clean" is what many consumers actually have experienced upon using the product, as shown by a consumer use survey conducted by an independent research firm. (Gallagher Dir. ¶ 20). According to that study, approximately 270 power toothbrush users were given an Ultreo to use on a trial basis for 30 days. (*Id.*; DX 3). A significant majority of those users indicated that the Ultreo made their teeth feel "cleaner" or "smoother." (Gallagher Dir. ¶¶ 23, 44).

25. Furthermore, "feeling of clean" claims are hardly unique to Ultreo. Many oral care companies – including P&G – claim that their products provide consumers with a "feeling of clean" or similar sensation. (Gallagher Dir. ¶ 45). For instance, P&G's advertisements for Scope claim that the mouthwash "leaves your breath feeling clean." (DX 10, 11). Similarly, P&G's advertising for its Crest toothpastes claims that they "leave[] teeth feeling clean." (DX 12). Indeed, P&G's Mr. Randall conceded that there was nothing inherently misleading about using a "feeling of clean" claim in advertisements. (Tr. at 90).

---

[4] Those claims include: (1) "Microbubbles are activated by the ultrasound and transformed into pulsating bubbles for an incredible feeling of clean;" or (2) "Ultreo's bristles create microbubbles that are powerfully activated by a patented ultrasound waveguide. The result is an incredible, long-lasting feeling of clean." (Gallagher Dir. ¶ 43).

E. Ultreo's Express Beyond-The-Bristles Claims To Professionals

26. Ultreo makes an express beyond-the-bristles claim to dental professionals based on laboratory research. (Gallagher Dir. ¶ 47). The claim is truthful because it is adequately supported by science which is recognized as valid by the industry.

1. The Industry Standard

27. The use of *in vitro* biofilm removal studies to support beyond-the-bristles claims in the oral care field is well established. For instance, Philips claims in its advertising that the dynamic fluid forces of the Sonicare clean plaque beyond the reach of its bristles. (Berg Dir. ¶¶ 20-22). Philips substantiates its beyond-the-bristles claims with laboratory studies that are virtually identical to the UW Study relied upon by Ultreo. (McInnes Dir. ¶¶ 15, 18-28).

28. Indeed, in October 2007, after this lawsuit was filed, Philips distributed a brochure directed to consumers that states:

> Powered by our patented sonic technology, Sonicare cleans beyond-the-bristles to remove plaque deep between the teeth and along the gumline.

(Tr. at 306-07; DX 14). The brochure also contained a visual image of the Sonicare "clean[ing] beyond-the-bristles." (DX 14). The advertisement does not even disclose that the claim is based on laboratory studies.

29. In September 2007, the same month in which P&G filed this lawsuit, Philips distributed a Compendium of research to the scientific community concerning its new FlexCare toothbrush. (Tr. at 247; DX 154K). The Compendium contains two *in vitro* biofilm removal studies that support the beyond-the-bristles cleaning capabilities of this new Sonicare toothbrush and, indeed, a beyond-the-bristles cleaning superiority claim *vis-à-vis* the Oral-B Triumph toothbrush. (DX 154K at 10).

30. Nowhere in the Compendium does Philips state or imply that the laboratory test results need to be corroborated by a clinical study. To the contrary, the Compendium confidently states that the *in vitro* biofilm removal methodology is reliably predictive since it "has been shown to reduce . . . plaque structures similar to those occurring on the tooth surface" and thus "provides a measure of the ability of an oral hygiene device to remove plaque biofilm accumulated in interproximal spaces." (DX 154K at 11).

31. Philips' current website is replete with beyond-the-bristles claims made on the basis of *in vitro* biofilm removal tests. When one visits the "Oral Care and Your Health" segment of the Sonicare *consumer* website and links on to the "Biofilm" website page, one is directed to view a short video of an *in vitro* plaque biofilm removal study showing the Sonicare's fluid forces removing *S. Mutans* from glass slides.[5] At the bottom of the page there is a "Read more about biofilm" link that links to three *in vitro* biofilm removal studies that support beyond-the-bristles claims. Annexed hereto at Exhibit B are copies of each of the relevant website pages referenced in this paragraph, as well as copies of the three *in vitro* studies relating thereto. The Court performed a similar exercise at the December 20 hearing session and printed out the webpages which are marked as DX 186.

32. Similarly, if one visits the "Dental Professionals" website page of the current Sonicare website and follows the link to "Clinical Studies," one can view abstracts of 24 Sonicare studies. Each time Sonicare makes a beyond-the-bristles and/or "fluid dynamic action" claim on the "Clinical Studies" page, the study cited to support that claim is an *in vitro* biofilm removal study. Copies of these website pages, as well as the studies referenced in the same, are annexed hereto at Exhibit C.

---

[5] The video is inscribed with a reference to the Adams Study (DX 154F), which involved an *in vitro* removal of *S. Mutans* from glass slides.

33. While the Philips website does contain reports of *in vivo* studies, those studies do not support, and are not used by Phillips to support, beyond-the-bristles claims. This was conceded by P&G's principal science witness at the hearing. (*See* Tr. at 767-70; Biesbrock agrees that support for Philips' beyond-the-bristles claims on its website are *in vitro* biofilm studies). (*See also* Tr. at 254; Genco: "I'd agree that Sonicare appeared to be making a claim for beyond-the-bristles cleaning based upon solely *in vitro* studies. I'm not aware of any *in vivo* or clinical studies that they have carried out in animals or man to substantiate that.") This point was also not seriously disputed by P&G's counsel:

> THE COURT: But I don't think these [summaries of *in vivo* studies] are 'Beyond the Bristles' studies. These are about just the effectiveness in removing plaque.
>
> MR. WILLIAMS: They may be, your Honor . . . .

(Tr. at 800-01) (*See also* Tr. at 877: Mr. Williams, admitting that there is "no question" that *in vitro* studies supporting beyond-the-bristles effects are contained on the Philips website.)

2. <u>P&G's Own Conduct</u>

34. Indeed, in the past, P&G itself has made beyond-the-bristles claims to the dental community based upon laboratory studies. (McInnes Dir. ¶ 19). Prior to acquiring the Oral-B brand in 2005, P&G jointly marketed a product with Philips ("IntelliClean") that combined a Sonicare toothbrush with a Crest brand toothpaste dispenser incorporated within the brush. (McInnes Dir. ¶¶ 19-20). In connection with the IntelliClean launch in 2004, P&G and Philips jointly published and disseminated to the dental community a "Compendium" of clinical and laboratory research regarding the product. The Compendium prominently discloses on its cover that the research contained therein was "[s]upported by . . . The Procter & Gamble Company." (DX 37).

35. The IntelliClean was not materially different from the standard Sonicare brush, the only difference being that the IntelliClean could dispense toothpaste directly to the bristles simply by pushing a button. (McInnes Dir. ¶ 20). It did not spray or "sho[o]t" toothpaste into the mouth, as Mr. Randall testified. (Tr. at 78). Indeed, as the Compendium explicitly states: "The Sonicare toothbrush within the IntelliClean System is built fundamentally in the same platform as the Sonicare Elite toothbrush." (DX 37 at 4).

36. In any event, the IntelliClean Compendium makes beyond-the-bristles claims not only for the new IntelliClean product, but for the regular Sonicare brushes as well. In marketing IntelliClean, P&G was obviously attempting to piggyback on years of Philips' sponsored *in vitro* research and beyond-the-bristles claims for the Sonicare toothbrushes. (Tr. at 162; Biesbrock: "[I]n IntelliClean, there was clearly a body of evidence that Philips had used historically to support *in vitro* claims of 'cleans beyond-the-bristles.'") The Compendium is replete with articles authored by P&G scientists stating that the Sonicare toothbrush (not the IntelliClean) has been proven to remove plaque bacteria beyond the bristles, with supporting citations to *in vitro* biofilm removal studies. (McInnes Dir. ¶¶ 21-28; Berg Dir. ¶¶ 24-25).

37. Indeed, the lead article in the Compendium, which is co-authored by a P&G Senior Scientist, explains that the standard Sonicare toothbrush "creates dynamic fluid activity in the mouth," and that "[a]ccording to in vitro studies . . . such fluid activity can remove plaque from beyond the reach of the bristles significantly better than a rotational-oscillation power toothbrush." (DX 37 at 5). That same article states that, "**[l]ike other Sonicare toothbrushes,** the IntelliClean System . . . has also been shown *in vitro* . . . to exhibit 'beyond-the-bristles' cleaning and to be gentle on dentin, significantly more so than the Oral-B ProfessionalCare 7000, a leading rotational oscillation toothbrush." (DX 37 at 7) (emphasis added).

38. The Compendium also includes the following statements, again not with respect to the new IntelliClean brush, but with respect to the standard Sonicare models:

> "In certain power toothbrushes, notably the Sonicare toothbrush, the brush's high-frequency motion not only cleans by direct bristle-tooth contact but also creates dynamic fluid pressure and shear forces that **have been shown** in laboratory studies to disrupt and disperse bacterial plaque beyond the reach of the bristles." (DX 37 at 8) (emphasis added).

> "Unlike many power toothbrushes, the Sonicare toothbrush was designed to deliver not only physical bristle contact with the teeth to remove plaque but also a fluid dynamic action derived from the bristle motion that **has been shown** *in vitro* to disrupt plaque biofilms." (DX 37 at 16) (emphasis added).

> "Previous studies using this [*in vitro*] methodology **have indicated** that this beyond-the-bristles biofilm removal effect was because of the fluid motion generated by the active motion of the bristles . . . ." (DX 37 at 49) (emphasis added).

39. Indeed, P&G's scientists refer to the hydrodynamic cleaning action of the Sonicare as "proven" based on laboratory studies. (DX 37 at 22). In response to the Court's questioning, Dr. Biesbrock admitted that the effect was "proven" by the *in vitro* studies, even if these results had not been replicated *in vivo*. (Tr. at 131-32; Biesbrock: "I think you can prove something *in vitro*. Our own *in vitro* studies are consistent with Ultreo's *in vitro* studies. So I think that phenomena in *in vitro* can be shown.")

40. Notably, nowhere in the Compendium is it stated that the results of the laboratory studies must be corroborated by clinical studies. Thus, at a time when its financial interests were different, P&G made the very claims that it now attacks as false, and relied upon the very science it now claims is invalid. Cognizant that P&G had flip-flopped on what is the central scientific issue in this case, Dr. Biesbrock tried to suggest that P&G was "not comfortable" with the statements made in the Compendium and that there was "concern" that the *in vitro* data were not reliable when the Compendium was prepared by P&G and distributed to dental professionals.

(Tr. at 162).[6] However, in response to the Court's questioning, he admitted that this discomfort and "concern" did not manifest itself anywhere in the Compendium. (Tr. at 163). He further acknowledged that P&G "support[s]" the Compendium since it had P&G's name on it (Tr. at 165), and "stands behind" the statements contained therein. (Tr. at 120). Finally, he admitted to the Court that he did not think it was "misleading" for P&G to have cited *in vitro* studies as supporting a claimed beyond-the-bristles efficacy. (Tr. at 164).

3. The Scientific Literature

41. Traditional, clinical plaque-removal studies are not designed to assess the relative capabilities of isolated, non-brushing technologies in a product. (Berg Dir. ¶¶ 18-19; McInnes Dir. ¶ 63). To date, there is no clinical test that has been used to measure and assess the beyond-the-bristles claims. Thus, Dr. Biesbrock testified: "I think a body of evidence could be built that would validate biofilm models with respect to what they mean clinically. Unfortunately, I don't think that's happened." (Tr. at 139). Dr. Genco, P&G's expert witness, further testified that he was not aware of any clinical test showing that the fluid forces of the Sonicare produce a health benefit in the month. (Tr. at 249). The reason for this shortcoming has been repeatedly explained in the scientific literature. Clinical studies utilize visible plaque indices that are insufficiently sensitive. (McInnes Dir. ¶¶ 62-64). Thus, as Drs. Hope, Petrie and Wilson have reported in their 2003 article published in the well-respected and peer-reviewed *Journal of Periodontology*:

> [T]he [visible plaque index] is qualitative; by definition, the index requires that the plaque must be visible to be scored and plaque deep within the meterproximal space (up to 5.15 mm from the site of bristle access to the center of the HA disc in our model) could not have been

[6] P&G also flip-flopped on the critical issue of Philips' advertising practices. (*See* Tr. at 509: "The Court: I have to say Mr. Williams' argument seems to have evolved from December that there were no clinical studies and that Philips wasn't making such claims to now Philips is making such claims, but they have clinical studies.").

> seen. A compounding factor is that the [visible plaque index] provides little scope for accurately measuring any reduction in the thickness of the plaque after brushing. Enumerating the number of biofilms provides a quantitative interrogatory of any reductions in the volume of the brushed plaque. (DX 154A at 1021).

42. More recently, in an article to be published in 2008 in the *Journal of Clinical Periodontology*, another respected, peer-reviewed journal, the authors state:

> Visible plaque indices (PI) have traditionally been used to clinically evaluate the effectiveness of these chemical and mechanical interventions . . . . Provided the tooth surfaces of interest are visually accessible, such as surfaces of anterior teeth, these indices can be considered sufficient. **However, scoring plaque in hard-to-see posterior interproximal areas is challenging, if not impossible with a visual index**. (DX 192 at 23) (emphasis added) (citations omitted).

43. Indeed, many dental research commentators have expressed a preference for *in vitro* testing since it is more controllable and more objective than clinical testing. Thus, as Drs. Hope and Wilson explained in their peer-reviewed article:

> **The *in vitro* system has the advantage of eliminating many problematic factors associated with *in vivo* clinical trials.** Major problems with *in vivo* studies of plaque removal include the poor reproducibility of results and the inability to standardize treatment. Natural variations in human dental plaque, both between subjects and day-to-day within a subject, also make brush comparisons challenging. A patient's personal preference for a particular brush may compromise objectivity. (DX 154G at 10B) (emphasis added).

44. Philips recognizes the limitations of clinical plaque removal studies. (Berg Dir. ¶ 18). While it has sponsored a number of clinical studies that evaluate the general efficacy of its product, it has never published any clinical study involving a group of human subjects, using the brush as directed, that purports to isolate and assess the benefits of its dynamic fluid forces. (Berg Dir. ¶ 19). Nor does it claim today that there is any clinical test supporting its beyond-the-

bristles cleaning capabilities of its product. (Berg Dir. ¶¶ 20-21).[7] Instead, laboratory studies are the sole basis upon which Philips relies to make beyond-the-bristles claims. (Berg Dir. ¶¶ 20-22).

45. Scientists have become comfortable with the predictive value of *in vitro* research as it pertains to beyond-the-bristles cleaning. (Tr. at 686; Berg Dir. ¶ 23). Thus, Dr. Adams stated that, based on results of her *in vitro* test, readers should expect a similar effect *in vivo*. (DX 154F at 17B). Similarly, P&G and Philips jointly touted the predictive value of *in vitro* plaque biofilm testing in the IntelliClean Compendium:

> The *in vitro* test methods applied here provide objective analysis of the efficacy and safety of these oral hygiene products . . . . **They provide methods of assessment of product efficacy representative of what would be found in the oral cavity.** (DX 154K at 50) (emphasis added).

46. Furthermore, the dental research community has grown skeptical of corporate-sponsored clinical plaque-removal studies because companies such as P&G and Philips never seem to publish tests reflecting adverse results and frequently publish test results that conflict with other published test results. (Berg Dir. ¶¶ 29-30). For instance, P&G's Oral-B website discloses the existence of 41 clinical studies comparing an Oral-B power toothbrush to a competing power or manual toothbrush, and P&G's record is an undefeated 40-0-1 in those clinical studies. (Berg Dir. ¶ 30). More importantly, P&G and Philips have each published clinical studies purporting to show that its brush outperforms the other. (Berg Dir. ¶ 31). These conflicting results have understandably led members of the research community to question the importance and value of comparative clinical research. (Berg Dir. ¶¶ 29, 32).

---

[7] After testifying at the December 19 hearing session that Philips had no clinical substantiation for its beyond-the-bristles claims (Tr. at 127, 139), Dr. Biesbrock tried to suggest in his rebuttal testimony on January 11 that there was such evidence. (Tr. at 767). When questioned by the Court about his sudden change of position, Dr. Biesbrock retreated, saying that he was not comfortable stating that the beyond-the-bristles effects of the Sonicare had been clinically substantiated. (*Id.*).

4. The UW Laboratory Test

47. The UW Study was conducted by experienced dental researchers from UW and by Dr. McInnes, who had been conducting *in vitro* biofilm removal studies for many years as a scientist at Optiva, Philips and now Ultreo. (McInnes Dir. ¶¶ 14-15).

48. The UW Study showed that the ultrasound-engaged Ultreo produced a statistically significant greater reduction in plaque bacteria without bristle contact than that produced by the Ultreo with the ultrasound disabled, the Sonicare Elite, or the Oral-B Triumph. (McInnes Dir. ¶¶ 16-17). All of the various parameters in the UW lab test had been used before in biofilm removal testing published in the scientific literature. The bacteria that was used, *S. Mutans*, a particularly prevalent, harmful and tenacious form of plaque bacteria, had been used in Adams, *et al.* (Tr. at 236-37; DX 154F). The saliva substitute, gastric mucin, had been used in Hope, *et al.* (Tr. at 228; DX 154A). The substrates used, hydroxyapatite disks, which contain the same mineral found in dentin and enamel, and glass slides, had been used by Hope, *et al.* (*id.*), and Adams, *et al.* (Tr. at 236-37; DX 154F), respectively.

49. Finally, the level of fluid (4-5ml) was comparable to levels used in Hope, *et al.* and Adams, *et al.* (Tr. at 228; DXs 154A, 154F). Dr. Biesbrock agreed that the level of fluid used in the UW Study approximated the amount of fluid that would exist in the mouth during normal toothbrushing. (Tr. at 144).

50. Although P&G repeatedly asserted that *S. Mutans* was different from the more complex forms of plaque that exist in the mouth, that gastric mucin was different from human saliva, and that hydroxyapatite disks were different from human teeth, P&G never submitted evidence showing that any such differences would likely affect the validity or results of the UW Study. Thus, for example, P&G submitted no evidence showing that *S. Mutans* would be easier to remove from a surface than more complex forms of plaque. P&G was free to modify the UW

Study in any way, and to use naturally-grown plaque, human saliva or extracted human teeth to see if the results would differ. It never did.[8]

51. Instead, P&G replicated the UW Study, using *S. Mutans* and hydroxyapatite disks, and obtained the same result. (McInnes Dir. ¶¶ 33-34). The ultrasound-activated Ultreo removed significantly more plaque bacteria without bristle contact than the Oral-B power toothbrush or the Ultreo with the power turned off. (DX 48). This result validates that the UW Study was properly conducted, and that its reported results are accurate. (Tr. at 132, 142).

52. Dr. McInnes and Dr. Berg have opined that the UW Study is sufficiently reliable to predict that the Ultreo's ultrasound removes plaque bacteria in the mouth. (McInnes Dir. ¶ 67; Berg Dir. ¶ 40). Professor Lawrence Crum, an expert on ultrasound, filmed a similar lab test so that the plaque bacteria removal effects of the ultrasonic activation of bubbles is visually identifiable, and opined that the methodology captured on film was reliably predictive as to what would occur in the mouth. (Crum Dir. ¶¶ 21-22).

F. Clinical Tests Do Not Refute the UW Study

1. P&G's Test

53. P&G erroneously contends that the clinical test it conducted on the Ultreo refutes the results of the UW Study. Clinical tests cannot be used to support or disprove beyond-the-bristles claims because visible indices of plaque removal are insufficiently sensitive to assess beyond-the-bristles effects. (McInnes Dir. ¶¶ 61-64). Consequently, clinical tests, whether conducted internally by Ultreo or by P&G, do not impeach the validity of the UW Study. (Tr. at 507-08).

---

[8] Indeed, Philips has refined the *in vitro* methodology, using multi-species biofilms, human saliva and extracted teeth, and has attained the same results as it achieved in the original test methodology. (Berg Dir. ¶¶ 34-35; DX 65)

54. Indeed, the clinical study conducted by P&G (using unblinded P&G employees as subjects), fails to demonstrate anything about the contribution of ultrasound to the Ultreo's plaque removal capabilities because it was not designed to measure that contribution. (McInnes Dir. ¶ 49). The P&G clinical test did not compare the Ultreo with the ultrasound component engaged to the Ultreo with the ultrasound disengaged. Instead, it compared the Ultreo with the power on to the Ultreo with the power off. (McInnes Dir. ¶ 49).

55. The P&G study also employed a protocol in which a hygienist held the Ultreo brushhead at distances from the subject's teeth. (McInnes Dir. ¶ 51). There are at least two fundamental problems with this approach that render the study fatally flawed. First, the protocol ensured that the waveguide was not in sufficient proximity to the majority of teeth to allow it to work. Second, the protocol ensured that there was insufficient fluid coupling, which is essential to the cleaning efficacy of the ultrasound. (McInnes Dir. ¶¶ 55-53).

2. Ultreo's Attorney Directed Clinical Work

56. The clinical studies conducted at the direction of Ultreo's counsel also do not impeach the validity of the UW Study. (Tr. at 510-12). Three of those studies were standard clinical plaque removal studies using traditional visible indices (Tr. at 674-76), which the scientific community and the industry have recognized are incapable of assessing the beyond-the-bristles cleaning effects of power toothbrushes. The last study was an experimental protocol involving a procedure that, as Dr. McInnes explained, involved too much variability to be able to assess the effects of the ultrasound generated by the Ultreo. (Tr. at 677).

G. Adequate Disclosure

57. Finally, Ultreo makes its beyond-the-bristles claim only to dental professionals. (Gallagher Dir. ¶ 47). In each instance, Ultreo clearly discloses that the claim is based upon an *in vitro* study. (*Id.* ¶ 48). Dental professionals are sufficiently knowledgeable and experienced

to appreciate whatever distinctions are relevant between *in vitro* and *in vivo* testing. P&G's Mr. Randall conceded this point (Tr. at 77-78), and Dr. Berg testified that dentists are taught the difference between laboratory and clinical research in dental school. (Tr. at 513).

58. Furthermore, Ultreo uses a qualifier such as "clinical relevance not established" whenever an advertisement makes reference to the specific results of the UW Study. (Tr. at 688). As Dr. McInnes explained, although Ultreo believes the UW Study is reliably predictive of what occurs in the month, it may not be predictive as to the amount of plaque that will be removed in the mouth. (*Id.*). For the same reason, Dr. McInnes explained, Ultreo also uses the qualifier whenever images of the glass slides or HA disks from the UW Study are visually presented. (*Id.* at 689).

59. By contrast, Philips does not include any type of qualifier to its beyond-the-bristles claims to consumers or dental professionals. (Tr. at 774). Nowhere in the FlexCare brochure (DX 136), the FlexCare Compendium (DX 154K) or its website (DX 186), does Philips state or imply that the clinical relevance of its beyond-the-bristles claims has not been established.

60. It is also noteworthy that P&G did not use such a qualifier in the IntelliClean Compendium (DX 37) or the IntelliClean brochure (DX 153). Clearly, P&G did not view it as necessary to use such a qualifier when it made beyond-the-bristles claims to dental professionals based on *in vitro* biofilm removal studies. Dr. Biesbrock opined that the IntelliClean Compendium was not misleading. (Tr. at 164).

61. Furthermore, there is no requirement that companies disclose their attempts to obtain clinical support for a beyond-the-bristles claim. In this regard, Philips has not publicly disclosed whether it has attempted to conduct clinical tests to support a beyond-the-bristles

cleaning claim. Similarly, P&G did not disclose any efforts it undertook to obtain clinical testing support for a beyond-the-bristles claim on the IntelliClean.

62. Indeed, P&G introduced into evidence several internal studies purportedly showing that its Pulsar and Sonic Vitality brushes were inferior to manual toothbrushes. (Tr. at 148-53; DX 7 at 25, 27). Neither of these studies is disclosed on P&G's website, which instead touts the plaque-removal efficacy of these products. (Tr. at 150-53, 780-81; DX 180). Nor does P&G disclose in its advertising for sonic toothbrushes the Cochrane Collaborative Study, which P&G claims shows that only oscillating/rotating power toothbrushes are superior to manual toothbrushes. (Tr at 778-80). Consequently, P&G is in no position to credibly assert that test results that are not supportive of a claim must be disclosed to consumers.

63. Finally, P&G claims that dental professionals are being misled because Ultreo sales personnel are being trained to respond to professionals who point to the absence of clinical support for a beyond-the-bristles claim. (Tr. at 25). There is, however, no evidence suggesting that Ultreo personnel are instructed to deny the absence of clinical support. Instead, these personnel are instructed to contend that, based on years of acceptance by the industry, *in vitro* research is reasonably predictive of what occurs in the mouth. (PX 31 at Ultreo 11155). There is nothing wrong with Ultreo communicating this viewpoint, which has support in the scientific literature, to dental professionals. The evidence shows that P&G is clearly communicating the opposing view to those professionals. For instance,

REDACTED

H. Irreparable Injury

64. All of the harm claimed by P&G in this case is easily quantifiable. P&G claims lost profits from lost sales, and it contends that it can identify those lost sales with a reasonable degree of precision. P&G presented no evidence of lost market share or price erosion. (Tr. at 72-73). As Dr. Mohan Rao, Ultreo's economics expert, testified: P&G cannot claim that it is being overwhelmed with advertising by Ultreo since Ultreo's total advertising budget of pales in comparison to P&G's budget on just two of its brushes, which is (Tr. at 595-96).

65. P&G's estimate of lost sales is based on the impact of Ultreo's entry into the market. (Tr. at 92-93). However, the pertinent issue is not whether Ultreo's entry into the market will impact P&G. Sales lost by P&G to a new market entrant are simply the consequence of lawful, healthy competition. (Rao Dir. ¶ 27). Instead, P&G must distinguish between the lost sales it believes it would experience from lawful competition (*i.e.*, truthful advertising), from the lost sales it believes it would sustain from the alleged false advertising. (Rao Dir. ¶¶ 27-30).

66. P&G has submitted no proof of causation between lost sales and Ultreo's advertising. (Tr. at 596). Indeed, P&G failed to submit any evidence of lost sales despite the fact that Ultreo has been in the market since February, 2007.

67. Rather, P&G originally contended that the Coulter Renken Study was an estimate of P&G's injury from false advertising. (Randall Decl. ¶ 23; P&G Moving Br. at 24). Once it was established that none of the allegedly offending ads was shown to the Coulter Renken respondents, P&G contended that Coulter Renken was an attempt to estimate its lost sales from lawful competition from Ultreo, and that any actual sales achieved by Ultreo in excess of that represented P&G's lost sales from false advertising. (Randall Supp. Decl. at ¶ 8).

68. This new theory of causation fares no better than the old one. The fact that Ultreo's actual sales may have exceeded the Coulter Renken estimate does not mean that the overage is the result of false advertising. (Tr. at 572-75). Coulter Renken's estimate could have simply been too low or Ultreo could have performed better than expectations for reasons other than the advertising claims. (Tr. at 835). Consequently, P&G's new theory of harm still fails to establish any logical causal link between the challenged advertising and lost sales. (Tr. at 596).

69. Mr. Gallagher testified that, of the sales he estimates Ultreo will make during its first full year, will be trial unit sales to dental professionals. (Tr. at 419, 442-43). Through December 31, 2007, Ultreo sold trial units. (Gallagher Supp. Decl., Ex. A; DX 195). These sales are made at deeply discounted prices so that the professional will use the product on a trial basis and compare it to other brushes. (Tr. at 420). Mr. Randall agreed that, in these circumstances, it cannot be said that those sales will displace P&G sales. (Tr. at 62-63).

70. Moreover, even if P&G did

(Tr. at 584-86).

This amount is plainly immaterial to a $76 billion company like P&G.

71. The laxity with which P&G has proceeded in this case also shows that there is no irreparable injury here. P&G first complained about Ultreo's advertising in March 2007, asserting that clinical studies were required to support any ultrasound-related advertising claims. (Gallagher Dir. ¶ 27). Yet, it was not until late September 2007 – a full six months later – that P&G commenced this action. (Gallagher Dir. ¶ 28).

72. The balance of the hardships sharply favors Ultreo. Ultreo has essentially no market share,

Contains Information Designated As "Confidential" Pursuant To November 9, 2007 Stipulated Confidentiality Order In This Action

REDACTED

Ultreo's sales during the pendency of this litigation are plainly inconsequential to P&G. (*Id.*, ¶ 30).

73. P&G also has unclean hands. It has engaged in the very same types of conduct about which it complains in this litigation. P&G has made advertising claims about its own oral care products citing laboratory studies, has extolled the benefits of beyond-the-bristles cleaning based on *in vitro* studies, and has regularly made "feeling of clean[ ]" advertising claims. (Gallagher Dir. ¶¶ 45, 52, 53, 57).

CONCLUSIONS OF LAW

A. No Likelihood Of Success On The Merits

74. To establish liability against Ultreo for a Lanham Act violation, P&G must first prove that Ultreo made the allegedly false statement. *See* 15 U.S.C. § 1125(a)(1)(B) ("Any person who . . . uses in commerce any . . . false or misleading representation of fact . . . ."). Liability for a Lanham Act violation by a third party requires proof that Ultreo intentionally induced another to engage in false advertising. *See Societe Des Hotels Meridien v. LaSalle Hotel Operating Partnership, L.P.*, 380 F.3d 126, 132-33 (2d Cir. 2004) (reversing dismissal of complaint for false advertising based on allegation that defendant "induced Starwood to violate the Lanham Act 'by intentionally directing, approving, authorizing, drafting and/or editing the Starwood Worldwide Directories'"). Thus, because there is no evidence that Ultreo induced a third party to make an allegedly false statement, Ultreo cannot be held liable for statements made by third parties about its product. *See Procter & Gamble v. Haugen*, 317 F.3d 1121, 1129-30 (10th Cir. 2003) (rejecting P&G's Section 43(a) liability claim against Amway where Amway did not instruct distributors to spread satanic rumors about P&G, and where Amway suggested

that one of its distributors issue a retraction); *NBA Properties v. Motorola,* 939 F. Supp. 1071, 1108-09 (S.D.N.Y. 1996) (rejecting NBA's Section 43(a) claim against Motorola where Motorola was not responsible for Brookstone's "facially false" statement in calling Sportrax information "officially licensed" by the NBA, and Motorola asked Brookstone to correct the error), *aff'd in part, vacated in part*, 105 F.3d 841 (2d Cir. 1997).

75. In order to establish the literal falsity of an establishment claim, the burden is on P&G to demonstrate that Ultreo's tests are "not *sufficiently reliable* to permit one to conclude with *reasonable certainty* that they established the proposition for which they were cited." *The P&G Co. v. Chesebrough-Pond's, Inc.*, 747 F.2d 114, 119 (2d Cir. 1984) (emphases supplied); *accord Glaxo Warner-Lambert OTC G.P. v. Johnson & Johnson Merck Consumer Pharms. Co.,* 935 F. Supp. 327, 329 (S.D.N.Y. 1996); *Nationwide Tarps, Inc. v. Midwest Canvas Corp.*, 228 F. Supp. 2d 202, 210 (N.D.N.Y. 2002). The Second Circuit has instructed the fact-finder to consider the "state of the testing art, [and] the existence and feasibility of superior procedures." *Chesebrough-Pond's,* 747 F.2d at 119. Here, both P&G and Philips, the market leaders in this category, have used *in vitro* biofilm removal tests to assess beyond-the-bristles effects and have never used a clinical study for that purpose.

76. Courts have held that advertising claims may be made on the basis of laboratory tests. *See L&F Products v. The P&G Company*, 845 F. Supp. 984, 992-93 (S.D.N.Y. 1994) (refusing to grant a preliminary injunction, noting that P&G was justified in relying upon its laboratory studies), *aff'd*, 45 F.3d 709 (2d Cir. 1995); *Playtex Prods., Inc. v. Gerber Prods. Co.*, 981 F. Supp. 827, 828-30 (S.D.N.Y. 1997) (denying a request for a preliminary injunction where the claim was supported by the defendant's laboratory testing); *Spalding Sports Worldwide, Inc. v. Wilson Sporting Goods Co.*, 198 F. Supp. 2d 59, 68 (D. Mass. 2002) (denying request for a preliminary injunction where laboratory test results supported the advertising claim).

77. Courts must consider the sophistication of a target audience in considering the veracity of advertising claims. In *P&G Pharmaceuticals, Inc. v. Hoffmann-La Roche*, No. 06-Civ-0034, 2006 WL 2588002, at **29-31 (S.D.N.Y. Sept. 6, 2006), this Court found that "the sophistication of the target audience [physicians] is one that is fully capable of discerning" the validity of study data. Similarly, in *Sandoz Pharmaceuticals Corp. v. Richardson-Vicks, Inc.*, 902 F.2d 222, 229-30 (3d Cir. 1990), the court held that,

> **a target audience's special knowledge of a class of products is highly relevant to any claim that it was misled by an advertisement for such a product.** [The plaintiff] never advanced any hard evidence that pediatricians would be misled by [the defendant's] information sheets or that they would believe that the assertions contained therein were supported by a greater degree of testing data than [the defendant] actually had compiled.

Id. (internal quotation omitted) (boldface added). Here, the dental professionals viewing Ultreo's advertisements know the difference between *in vitro* and *in vivo* testing methodologies. They are fully capable of forming their own opinions as to the reliability of the UW Study.

78. Subjective or exaggerated statements about a product constitute puffery, which is not actionable under the Lanham Act. *Time Warner Cable, Inc. v. DIRECTV, Inc.*, 497 F.3d 144, 159-61 (2d Cir. 2007). A "feeling of clean" is a subjective perception that is puffery. *See The Gillette Co. v. Wilkinson Sword, Inc.*, 89-Civ-3586, 1989 WL 82453, at *4 (S.D.N.Y. July 6, 1989) (claim that shaver provided the "'smoothest, most comfortable shave possible'" is permissible as "mere 'puffing'"). Similarly, use of the term "magic" is puffery. *See Dessert Beauty Inc. v. Fox*, No. 05-Civ-3872, 2007 WL 2244870, at *7 n.2. (S.D.N.Y. Aug. 6, 2007).

79. Because P&G has admitted that Ultreo's express statements to consumers are literally true, its case with regards to Ultreo's consumer advertising rests on the premise that Ultreo made impliedly false statements to consumers. A plaintiff that relies on a theory of implied falsity must introduce into evidence a competent consumer survey to prove that

consumers take away a certain implied message. *Johnson & Johnson * Merck Consumer Pharms. Co. v. Smithkline Beecham Corp.*, 960 F.2d 294, 297-98 (2d Cir. 1992). The Dupont Survey utterly fails in this regard. Moreover, a court may not substitute its own judgment or reaction to the advertisement's message for that of consumers. *Id.*

80. Dr. Dupont's consumer survey is flawed and unreliable because he failed to use a control. In *Pharmacia Corp. v. GlaxoSmithKline Consumer Healthcare, LP*, 292 F. Supp. 2d 594, 601, 601-05 (D.N.J. 2003), the court held that a consumer survey conducted by Dr. Dupont was flawed and unreliable because he failed to adequately control for pre-existing beliefs. As the court explained, "because of this control failure," it "cannot determine if consumers actually perceived" the allegedly implied message in the advertisement at issue or "if they were led to perceive one that was not there as a result of their pre-existing biases." *Id.* at 605; *see also SmithKline*, 960 F.2d at 301 (control "functions as a baseline and provides a measure of the degree" to which respondents' answers are influenced by factors other than the advertisement, "such as the survey's questions, the survey's procedures, the nature of the product or some other potential influence on a respondent's answer such as pre-existing beliefs").

81. Dr. Dupont's survey is also flawed because it employed leading questions. In *Smithkline*, the Second Circuit affirmed the district court's rejection of a consumer survey because it employed leading questions. 960 F.2d at 300. The district court noted that very few consumers perceived the alleged implied message when asked objective, non-leading questions, such as "what are the main ideas the commercial communicates to you" or "what other ideas does the commercial communicate to you." However, that number grew significantly when a series of "somewhat leading" and "very leading" follow-up questions were asked such as "what, if anything, does the commercial communicate to you about aluminum and magnesium" and "how do you feel about taking a product for heartburn that contains aluminum and magnesium."

The Second Circuit agreed with the district court's conclusion that the responses to the initial non-suggestive questions were the "most persuasive evidence of the message communicated" by the ad. *Id.*

82. Only six percent of respondents to Dr. Dupont's first question claimed that the ad communicated that ultrasound/bubbles/sonic vibrations removes plaque. This figure is inflated because it includes persons who reacted to the mechanical sonic bristle action of the Ultreo, not merely the ultrasound or the bubbles. Regardless, this falls well short of the 20-25% threshold required to prove consumer misperception. *See Johnson & Johnson*Merck Consumer Pharmaceuticals Co. v. Rhine Poulenc Roier Pharms., Inc.*, 19 F.3d 125, 134 n.14 (3d Cir. 1994); *R.J. Reynolds Tobacco Co. v. Lowes Theatres, Inc.*, 511 F. Supp. 867, 876 (S.D.N.Y. 1980).

83. Moreover, P&G cannot obtain injunctive relief since it engaged in the same form of commercial conduct about which it complains. *See Haagen-Dazs, Inc. v. Frusen Gladje Ltd.*, 493 F. Supp. 73, 76 (S.D.N.Y. 1980); *Emco, Inc. v. Obst*, CV03-6432-R, 2004 WL 1737355, at **5-6 (C.D. Cal. Jul. 29, 2004).

84. P&G is not likely to succeed on the merits of claims that Ultreo's advertising is allegedly false or misleading and is a violation of Section 43(a) of the Lanham Act.

B. No Irreparable Injury

85. To establish irreparable harm, "[t]he likelihood of injury and causation . . . must be demonstrated in some manner." *DIRECTV, Inc.*, 497 F.3d at 161 (citation omitted). P&G must demonstrate "a logical causal connection between the alleged false advertising and [its] own sales position." *McNeil-PPC, Inc. v. Pfizer, Inc.*, 351 F. Supp. 2d 226, 247 (S.D.N.Y. 2005) (citation omitted); *see also DIRECTV,* 497 F.3d at 162. P&G has failed to meet its burden.

P&G has adduced no evidence of any lost sales that are logically causally attributable to Ultreo's advertising claims. In fact, P&G has not even shown that its sales have declined since Ultreo entered the marketplace.

86. P&G's alleged lost sales are, in any event, *de minimus*. Courts typically require that plaintiffs demonstrate a loss of market share, as opposed to mere loss of sales, to obtain a preliminary injunction against advertising. *See Coca-Cola Co. v. Tropicana Products, Inc.*, 690 F.2d 312, 317 (2d Cir. 1982) (likelihood of lost market share) (*abrogated on other grounds*); *S.C. Johnson & Son, Inc. v. Clorox Co.*, 930 F. Supp. 753, 786 (E.D.N.Y. 1996) (lost market share); *Novartis Consumer Health, Inc. v. Johnson & Johnson*, 290 F.3d 578, 595-96 (3d Cir. 2002) (loss of market share constitutes irreparable harm); *Moltan Co. v. Eagle-Picher Indus.*, 55 F.3d 1171, 1175 (6th Cir. 1995) (loss of market share); *Cordis Corp. v. Medtronic, Inc.*, 835 F.2d 859, 864 (Fed. Cir. 1987) (loss of market share).

87. Furthermore, P&G's delay in seeking injunctive relief shows the absence of any irreparable injury. *See Citibank, N.A. v. Citytrust,* 756 F.2d 273, 276-77 (2d Cir. 1985) (finding that 10 week delay in seeking a preliminary injunction suggests that there is, in fact, no irreparable injury); *accord Tough Traveler, Ltd. v. Outbound Prods.*, 60 F.3d 964, 968 (2d Cir. 1995); *see also Magnet Communications LLC v. Magnet Communications, Inc.*, No. 00-Civ-5746, 2001 WL 1097865, at *1 (S.D.N.Y. Sept. 19, 2001) (delay of 12 weeks); *ImOn, Inc. v. ImaginOn, Inc.*, 90 F. Supp. 2d 345, 350 (S.D.N.Y. 2000) (delay of 18 weeks); *The Comic Strip, Inc. v. Fox Television Stations, Inc.*, 710 F. Supp. 976, 981 (S.D.N.Y. 1989) (delay of 3 months).

88. Preliminary injunction relief is not appropriate with respect to advertisements that have been discontinued or modified to remove the objectionable content. *Twentieth Century Fox Film Corp. v. Suarez Corp.*, 46 U.S.P.Q.2d 1312, 1314-16 (S.D.N.Y. 1998) (defendant consented to remove offending advertisement from its website); *Novartis Consumer Health, Inc. v. Johnson*

& Johnson-Merck Consumer Pharm. Co., 129 F. Supp. 2d 351, 359 (D.N.J. 2000) (preliminary injunction denied in light of discontinuance of advertising claims and representations as to future conduct); *American Express Travel Related Servs. Co. v. MasterCard Int'l Inc.*, 776 F. Supp. 787, 789-91 (S.D.N.Y. 1991) (preliminary injunction denied since commercial was revised); *Coors Brewing Co. v. Anheuser-Bush Cos.*, 802 F. Supp. 965, 970 (S.D.N.Y. 1992) (preliminary injunction denied based on defendant's representation as to future use of commercial).

Dated: New York, New York
February 1, 2008

Respectfully submitted,

WINSTON & STRAWN LLP

By: _____

Anthony DiSarro
Lina M. Viviano
200 Park Avenue
New York, New York 10166
(212) 294-6700
adisarro@winston.com
lviviano@winston.com

Kimball R. Anderson
Stephen P. Durchslag
35 West Wacker Drive
Chicago, Illinois 60601

and

Marc C. Levy
Kirkpatrick & Lockhart Preston Gates Ellis LLP
925 Fourth Avenue, Suite 2900
Seattle, Washington 98104

Attorneys for Defendant Ultreo, Inc.